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12	Bard Peripheral Vascular, Inc.									
13	IN THE UNITED STATES DISTRICT COURT									
14	FOR THE DISTRIC	T OF ARIZONA								
15	IN RE: Bard IVC Filters Products Liability Litigation,	No. 2:15-MD-02641-DGC								
16		DEFENDANTS' RESPONSE IN OPPOSITION TO PLAINTIFFS'								
17	This Document Relates to:	MOTION IN LIMINE NO. 4 TO EXCLUDE OR LIMIT								
18	Lisa Hyde, et al. v. C. R. Bard, Inc., et al. CV-16-00893-PHX-DGC	ARGUMENT AND EVIDENCE REGARDING BARD'S G2X AND								
19		ECLIPSE INFORMATION FOR USE								
20		(Assigned to the Honorable David G.								
21		Campbell)								
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Bard's G2X and Eclipse Filter IFUs are relevant to multiple causes of action and Bard's defense for many, independent reasons. As such, Plaintiffs' Motion should be denied.

First, under Wisconsin law, an element for Plaintiffs' strict liability design-defect claim is whether the "foreseeable risks of harm posed by the product's design could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). This language is taken nearly verbatim from section two of the *Restatement (Third) of Torts*, which requires a "risk-utility balancing" test and consideration of a "broad range of factors," including "the instructions and warnings accompanying the product." Id. § 2(b), cmts. d, f; see Uniroyal Goodrich Tire Co. v. Martinez, 977 S.W.2d 328, 337 (Tex. 1998) (citing comment f, noting that "we agree with the new Restatement that warnings and safer alternative designs are factors, among others, for the jury to consider in determining whether the product as designed is reasonably safe"). Plaintiffs acknowledge in their Motion that Bard's IFUs contain "directions for use, indications for use, removal procedures, clinical experience regarding removal, precautions, warnings, [and] potential complications," and that the IFU accompanied the filter at issue "in the product packaging to offer guidance for physicians" implanting" it. (See Doc. 12100, p. 2 lines 7–9, 20–21). Thus, the contents of the IFUs are relevant to the jury's analysis of the factors bearing on whether the filter was "reasonably safe" under Wisconsin's strict-liability statute.<sup>1</sup>

Second, Wisconsin's strict-liability statute contains an enumerated defense requiring dismissal if the damage was caused by the product's "inherent characteristic" which "an ordinary person with ordinary knowledge common to the community that uses

<sup>&</sup>lt;sup>1</sup> Wisconsin's product liability statute clearly adopted the risk-utility test under the Restatement (Third) of Torts. Under the Restatement (Third) of Torts' risk-utility test, "consumer expectations" is a non-dispositive factor that the jury may consider. Because the IFUs discuss the risks attendant to the use of the filters, the IFUs are relevant to determining what risks physicians/consumers expect Bard's filters to carry.

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or consumes the product" would recognize. Wis. Stat. § 895.047(3)(d). The IFUs are relevant to this defense because they discuss the risks inherent to the filter and accompany each filter to inform all physicians who use the product about these risks.

Third, Bard's IFUs are also relevant to Plaintiffs' negligent design claim. Because manufacturers are held to a "reasonable person" standard of customary methods of manufacture in a similar industry, industry custom and the state of the art are admissible to "provide evidence to the jury about whether the defendant reasonably could have done something to prevent the harm." *Morden v. Cont'l AG*, 611 N.W.2d 659, 675 (Wis. 2000). And Wisconsin's Supreme Court recognizes that "negligence claims require a risk-benefit analysis." Green v. Smith & Nephew AHP, Inc., 629 N.W.2d 727, 751 (Wis. 2001). Bard's IFUs depict state of the art and industry custom in the medical device industry at the time of the filter's manufacture, and are thus relevant to the jury's determination of negligence. Also, Bard's IFUs contain information about "warnings," "potential complications," and "clinical experience," demonstrating the risk of potential complications inherent to the product's design, making them relevant to the jury's risk-benefit analysis.

Plaintiffs' argument that Bard's IFUs should not be admissible under Rule 403 because they might confuse and mislead the jury "into believing that the defendants have a defense to a claim that no longer exists" is unpersuasive because the IFUs also are relevant to Plaintiffs' design-related claims, as discussed above. (See Doc. No. 12100, p. 3 lines 9–10). Finally, without any explanation, on the last line of their Motion, Plaintiffs cite to the hearsay rules, presumably as a reason that the IFUs should not be admissible. But Bard's IFU are not hearsay under Rule 801 because they need not be admitted for the truth of the matter asserted, but rather can be admitted to demonstrate the reasonableness of Bard's conduct and industry custom. And even if the IFUs were offered for the truth of the matter asserted, they should be admissible as records of a regularly conducted activity. See Fed. R. Evid. 801, 803(6).

For these reasons, Plaintiffs' Motion in Limine No. 4 should be denied.

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I hereby certify that on this 28th day of August 2018, the foregoing was electronically filed with the Clerk of Court using the CM/ECF system which will automatically send e-mail notification of such filing to all attorneys of record.

<u>s/Richard B. North, Jr.</u> Richard B. North, Jr.